

### **REMARKS/ARGUMENTS**

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment has corrected a typographical error in claim 53 and has inserted additional words merely for the purpose of clarifying the claimed subject matter. These amendments overcome the claim objection stated in the final office action and, additionally, place the claims in better form for appeal. In view of these amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

The Final Office Action stated that claims 53-58 and 61-63 were rejected as being anticipated by, or in the alternative, obvious over United States Patent No.5,464,395 (Faxon et al.). The Office Action acknowledges that Faxon et al. fails to disclose the claimed imageable marker(s) but states that:

“inherently (as a matter of routine in the art) one or more imageable (such as radiopaque) markers useable in conjunction with an imaging apparatus (such as by fluoroscope x-ray) to facilitate the adjustment of the rotational orientation of the catheter body within the blood vessel so that subsequent advancement of the tissue penetrating element will cause the tissue penetrating element to advance in the direction of the target location. If the marker and imager are not considered inherent, it is well known in the art to image a catheter using radiopaque markers and a fluoroscope to view and guide a catheter and therefore would have been obvious.

Applicant respectfully disagrees with this reasoning. If it were “inherent” or a “matter of routine in the art” to use markers in conjunction with an imaging apparatus (such as by fluoroscope x-ray) to facilitate the adjustment of the rotational orientation of the catheter body within the blood vessel so that subsequent advancement of the tissue penetrating element will cause the tissue penetrating element to advance in the direction of the target location, as the Office Action states, there should certainly be at least one prior art reference that describes or suggests such a concept. However, the USPTO has not been able to cite any prior art that describes or suggests this concept.

In the system of independent claim 53, a tissue penetrating element that has a lumen is advanceable from a first (retracted) position to a second (extended) position. The claimed imageable marker(s) are constructed to provide an indication of the trajectory on which the tissue penetrating element will advance while the tissue penetrating element is still in the first position. This enables the operator to adjust the rotational orientation of the catheter body within the blood vessel while the penetrating element is still in the first position so that subsequent advancement of the tissue penetrating element to the second position will cause the tissue penetrating element to advance in the intended direction and not some other non-intended direction. The system of claim 53 also includes a guidewire that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position.

Specific non-limiting examples of the claimed marker(s) are shown in Figures 4D-4K and 6-6D and described in the accompanying detailed description of those figures.

Faxon et al. fails to describe or even remotely suggest any imageable markers that are useable in conjunction with an imaging apparatus to facilitate adjustment of the rotational orientation of his device within the body lumen so that subsequent advancement of his needle cannula will cause the needle cannula advance in the direction of a particular target location. Nor are the claimed imageable marker(s) “inherent” in the disclosure of Faxon et al. The United States Court of Appeals for the Federal Circuit has specifically held that the Office bears the burden of proving inherency and that the merely because a missing element could be used in conjunction with the cited reference does not render that missing element inherent.

Rather, to establish inherency, the Office must provide extrinsic evidence which makes it clear that the alleged “inherent” element would necessarily be present in whatever is explicitly described in the reference and that it would be so recognized by persons of ordinary skill in the relevant art. Furthermore, inherency may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). The claimed imageable marker(s) is/are in no way “inherent” in the Faxon et al. reference and the Office Action makes refers to absolutely

no extrinsic evidence to support the position that the claimed imageable marker(s) is/are inherent.

Furthermore, apart from the issue of inherency, there is absolutely no basis for the assertion that use of the claimed imageable markers would be “routine in the art” and thus should be somehow read into the Faxon et al. reference to provide support the obviousness rejection. In reality, Faxon et al. fails to describe the claimed imageable marker(s) and fails to even recognize the need for or desirability of including such imageable marker(s).

The United States Supreme Court has discussed the rationale for obviousness rejections in *KSR International Co. v. Teleflex Inc.*, 550 U.S. at 1, 82 USPQ2d at 1391 (2007). In *KSR*, the Court affirmed and reiterated the objective analysis for determining obviousness under 35 U.S.C. 103 as stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), whereby obviousness is a question of law based on underlying factual inquiries. The *Graham* factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art.

Recognizing that the Office personnel fulfill the critical role of fact finder when resolving the *Graham* inquiries, the Office has established Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR*. These guidelines became effective October 10, 2007 and are to be followed by patent examiners when rejecting claims on grounds of obviousness. Noting the need for explicitly stated rejections, these guidelines state as follows:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

The Office Action fails to state explicit findings sufficient to support the rejection as required under KSR and the Office guidelines. Specifically, with respect to obviousness rejections that are, as in the present case, based on the hypothetical addition of a purportedly known element (e.g., imageable marker(s) that provide an indication of the expected penetrator trajectory while the penetrator is still in its withdrawn position within the catheter) to a base prior art device (e.g., the Faxon et al. device), the Office guidelines state as follows:

To reject a claim based on this rationale, Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following:

- (1) a finding that the prior art contained a “base” device (method, or product) upon which the claimed invention can be seen as an “improvement;”
- (2) a finding that the prior art contained a “comparable” device (method, or product that is not the same as the base device) that was improved in the same way as the claimed invention;
- (3) a finding that one of ordinary skill in the art could have applied the known “improvement” technique in the same way to the “base” device (method, or product) and the results would have been predictable to one of ordinary skill in the art; and
- (4) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

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The final office action fails to comply with the Office guidelines because it does not articulate any findings of the Graham factors and fails to identify any “comparable” device in the prior art that was improved in the same way as the claimed invention (i.e., by addition of the claimed imageable marker(s) that provide an indication of the penetrator trajectory while the penetrator is still in its withdrawn position. Thus, the Office Action fails to state a sustainable obviousness rejection and fails to provide sufficient information to allow

Applicant to respond fully to the stated rejection. On these grounds alone, the stated rejection should be withdrawn.

Additionally, Faxon et al. failed to describe any guidewire that advances through the lumen of a penetrator after the penetrator has been advanced to a target location. At page 3 of the final Office Action, the Examiner contends that Faxon et al. does, in fact, teach a “guidewire (45) that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position.” This is simply incorrect. The guidewire (45) of Faxon et al. extends through a lumen in the catheter body and is useable for guiding advancement of the entire catheter. It does not extend through any lumen of any tissue penetrator that extends from the catheter body. Thus, Faxon et al. also fails to describe or render obvious the guidewire element of independent claim 53.

### **CONCLUSION**

For the foregoing reasons, Applicants believe all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484.

Respectfully submitted,

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